



DEC 22 2010

4 510(k) Summary of Safety and Effectiveness

Date Summary Prepared	December 15, 2010
Purpose of Submission	To obtain clearance of a 5 mm Arthrex Univers II Shoulder Prosthesis
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Sally Foust, RAC Regulatory Affairs Project Manager Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1251 Fax: 239/598.5508 Email: sfoust@arthrex.com
Trade Name	Arthrex Univers II Shoulder Prosthesis
Common Name	Shoulder Prosthesis
Product Code -Classification Name	KWS – Prosthesis, Shoulder, semi constrained metal/polymer, cemented HSD – Prosthesis, Shoulder, hemi-humeral, metal, uncemented
Predicate Devices	Arthrex Univers II Shoulder Prosthesis, K071032
Device Description and Intended Use	<p>Device Description: The Arthrex Univers II Shoulder Prosthesis is a 5 mm one-piece titanium alloy humeral stem that is 105 mm long and is designed with a distal conical section, a proximal rectangular section, and with a morse-taper for mating with humeral heads. The stem's surface finish is textured for cemented or press-fit (non-cemented) implantation.</p> <p>Intended Use: The Arthrex Univers II Shoulder Prosthesis is indicated in replacements(s) when conditions include severe pain or significant disability resulting from degenerative, rheumatoid, traumatic disease, or injury of the glenohumeral joint; non-union humeral head</p>



fractures of long duration; irreducible 2- and 4-part proximal humeral fractures; avascular necrosis of the humeral head; or other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable. The glenoid components are designed for cemented fixation in the joint and must only be used with an appropriate bone cement.

**Substantial Equivalence
Summary**

The **Arthrex Univers II Shoulder Prosthesis** is substantially equivalent to the predicate Arthrex Univers Shoulder Prosthesis, in which the basic features and intended uses are the same. The smaller size and the one-piece design when compared and tested to the larger and modular predicate Arthrex Univers II Shoulder Prosthesis was determined to not raise questions concerning safety and effectiveness. Based on design controls and fatigue testing comparison, Arthrex, Inc. has determined that the new **Arthrex Univers II Shoulder Prosthesis** is substantially equivalent to the currently marketed predicate device, Arthrex Univers II Shoulder Prosthesis (K071032).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Arthrex, Inc.
% Ms. Sally Foust, RAC
Regulatory Affairs Project Manager
1370 Creekside Boulevard
Naples, Florida 34108-1945

DEC 22 2010

Re: K103466

Trade/Device Name: Arthrex Univers II Shoulder Prosthesis
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD
Dated: November 24, 2010
Received: November 24, 2010

Dear Ms. Foust:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

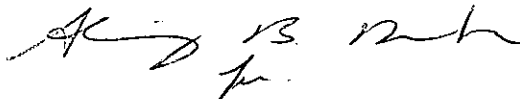
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3 Indications for Use Form**Indications for Use**510(k) Number (if known): K103466Device Name: Arthrex Univers II Shoulder Prosthesis

The Arthrex Univers II Shoulder Prosthesis is indicated in replacements(s) when conditions include severe pain or significant disability resulting from degenerative, rheumatoid, traumatic disease, or injury of the glenohumeral joint; non-union humeral head fractures of long duration; irreducible 2- and 4-part proximal humeral fractures; avascular necrosis of the humeral head; or, other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable.

The glenoid components are designed for cemented fixation in the joint and must only be used with an appropriate bone cement.

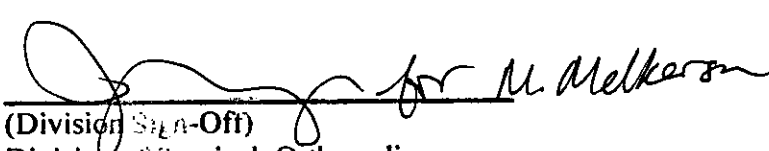
Prescription Use ☒ AND/OR Over-The-Counter Use ☐

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON
ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103466